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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,912	11/28/2001	John W. Shultz	PRMG-06684	1565

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,912

Applicant(s)

Shultz

Examiner

Arun Chakrabarti

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 7, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-61 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0703 6) ☒ Other: Detailed Action

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DETAILED ACTION

Status of the Application

1. The amendment received on July 7, 2003 has been entered. Claims 1-23 has been canceled without prejudice towards further prosecution. New claims 24-61 have been added.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 24-38, 40, 43, 44, 49-56, and 58 are rejected under 35 U.S.C. 102 (b) as being anticipated by Raines et al. (U.S. Patent 5,389,537) (February 14, 1995).

Raines et al teach a method for reducing the activity of an RNase (Abstract), comprising:

a) providing

- i) a preparation comprising at least one RNA homopolymer and heteropolpolymer (Column 4, lines 42-66, Table 1 and Column 8, lines 34-47);

ii) a sample containing an RNase from a cell (Examples); and

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b) mixing the preparation with the sample under conditions such that the activity of the RNA binding enzyme is diminished relative to the activity of the RNase in the absence of the RNA polymer (Column 4, lines 42-66).

Raines et al teach a method, wherein the RNA polymers are selected from poly A, poly U and poly C (Table 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 41, 45-48, and 59 are rejected under 35 U.S.C. 103(a) over Raines et al. (U.S. Patent 5,389,537) (February 14, 1995) in view of Berger et al. (Biochemistry, (1979), Vol. 18 (23), pages 5143-5149).

Raines et al. teach the method of claims 24-38, 40, 43, 44, 49-56, and 58 as described above.

Raines et al do not teach a method for reducing the activity of an RNase, wherein the activity of the RNase is diminished at least 25-90% relative to the activity of the RNase in the absence of the RNA polymer.

Berger et al. teach a method for reducing the activity of an RNase, wherein the activity of the RNase is diminished at least 25-90% relative to the activity of the RNase in the absence of the RNA polymer (Figure 1 and Table 1).

Raines et al do not teach a method for reducing the activity of an RNase from a tumor cell.

Berger et al teach a method for reducing the activity of an RNase from a tumor cell (Page 5148, Column 2, Discussion Section).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine a method for reducing the activity of an RNase, wherein the activity of the RNase is diminished at least 25-90% relative to the activity of the RNase in the absence of the RNA polymer of Berger et al in the method of Raines et al. since Berger et al. state, "The use of this inhibitor should therefore be considered for all tissues in which

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ribonucleases impede isolation of intact RNA (Abstract, last sentence)". An ordinary practitioner would have been motivated to substitute and combine a method for reducing the activity of an RNase, wherein the activity of the RNase is diminished at least 25-90% relative to the activity of the RNase in the absence of the RNA polymer of Berger et al in the method of Raines et al. in order to achieve the express advantages noted by Berger et al. of an inhibitor which should be considered for all tissues in which ribonucleases impede isolation of intact RNA.

6. Claims 42 and 60 are rejected under 35 U.S.C. 103(a) over Raines et al. (U.S. Patent 5,389,537) (February 14, 1995) in view of Chatterjee et al. (U.S. Patent 5,965,399) (October 12, 1999).

Raines et al. teach the method of claims 24-38, 40, 43, 44, 49-56, and 58 as described above.

Raines et al do not teach the method, wherein RNase comprises RNase A, B or angiogenin.

Chatterjee et al. teach the method, wherein RNase comprises RNase A, B or angiogenin (Column 1, lines 34-48).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method, wherein RNase comprises RNase A, B or angiogenin of Chatterjee et al in the method of Raines et al. since Chatterjee et al. state, "RI is useful in a variety of molecular biology applications where RNase contamination is a potential problem (Column 1, lines 39-41)". An ordinary practitioner would have been motivated

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to substitute and combine the method, wherein RNase comprises RNase A, B or angiogenin of Chatterjee et al in the method of Raines et al. in order to achieve the express advantages noted by Chatterjee et al. of RI which is useful in a variety of molecular biology applications where RNase contamination is a potential problem.

7. Claims 39, 57 and 61 are rejected under 35 U.S.C. 103(a) over Raines et al. (U.S. Patent 5,389,537) (February 14, 1995) in view of Akitaya et al. (U.S. Patent 6,300,058 B1) (October 9, 2001).

Raines et al teach the method of claims 24-38, 40, 43, 44, 49-56, and 58 as described above.

Raincs et al do not teach the method, wherein the ribonuclease inhibitor is RNASIN.

Akitaya et al. teach the method, wherein the ribonuclease inhibitor is RNASIN (Column 9, lines 1-46).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method, wherein the ribonuclease inhibitor is RNASIN of Akitaya et al in the method of Raines et al. since Akitaya et al. state, "mRNA in the preparations of lanes 1 (containing RNASIN) and 2 did not experience substantial mRNA degradation (Column 9, lines 45-46)". An ordinary practitioner would have been motivated to substitute and combine the method, wherein the ribonuclease inhibitor is RNASIN of Akitaya et al in the method of Raines et al. in order to achieve the express advantages, as noted by Akitaya et al. of RNASIN which prevents substantial mRNA degradation.

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Response to Amendment

8. In response to amendment, all previous rejections have been withdrawn. However, new 102(b) and 103(a) rejections have been included.

Response to Arguments

9. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the LIE Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 746-4979. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634
August 15, 2003


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